

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

JAMES SHANTZ,

Plaintiff,

vs.

Civil Action No.:

TAKEDA PHARMACEUTICALS USA, INC.
f/k/a TAKEDA PHARMACEUTICALS
NORTH AMERICA, INC.,

JURY TRIAL DEMANDED

TAKEDA PHARMACEUTICALS AMERICA,
INC.,

TAKEDA GLOBAL RESEARCH &
DEVELOPMENT CENTER, INC., and

TAKEDA PHARMACEUTICALS
INTERNATIONAL, INC.

Defendants.

COMPLAINT

AND NOW, comes the Plaintiff, James Shantz, by and through his undersigned counsel, and files the following Complaint, and avers as follows:

JURISDICTION AND VENUE

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds \$75,000.00, exclusive of interest and costs, and because complete diversity exists between the parties, as the Defendants are incorporated and have their principal places of business in states other than the state in which the Plaintiff resides. Plaintiff is a citizen of the United States of America, and a resident of Zelienople, Butler County in the state of Pennsylvania.

2. Venue is proper within this District under 28 U.S.C. § 1391 because it is a judicial

district where Defendants are subject to personal jurisdiction in accordance with 28 U.S.C. § 1391(c).

NATURE OF THE CASE

3. This personal injury action is brought on behalf of Plaintiff, James Shantz, who used Actos, also known as pioglitazone hydrochloride, for treatment of Type 2 Diabetes Mellitus.

4. Defendants, Takeda Pharmaceuticals USA, Inc. f/k/a Takeda Pharmaceuticals North America, Inc.; Takeda Pharmaceuticals America, Inc.; Takeda Global Research & Development Center, Inc.; and Takeda Pharmaceuticals International, Inc. (hereinafter collectively referred to as “Defendants”) designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Actos, a Diabetes medication used by Plaintiff which was a substantial contributing factor in causing his bladder cancer.

5. When warning of safety and risks of Actos, Defendants negligently and/or fraudulently represented to the medical and healthcare communities, the Food and Drug Administration (hereinafter referred to as “FDA”), to Plaintiff and the public in general, that Actos had been tested and was found to be safe and/or effective for its indicated use.

6. Defendants concealed their knowledge of Actos’ defects from Plaintiff, the FDA, the public in general and/or the medical and healthcare community specifically.

7. These representations were made by Defendants with the intent of defrauding and deceiving Plaintiff, the FDA, the public in general, and the medical and healthcare communities in particular, and were made with the intent of inducing the public in general, and the medical and healthcare communities in particular, to recommend, dispense and/or purchase Actos for use as treatment of Type 2 Diabetes Mellitus, all of which evidence a callous, reckless, willful, and depraved indifference to health, safety and welfare of Plaintiff herein.

8. Defendants negligently and improperly failed to perform sufficient tests, if any, on humans using Actos during clinical trials, forcing Plaintiff, and Plaintiff's physicians, hospitals, and/or the FDA, to rely on safety information that applies to other Type 2 Diabetes Mellitus treatment, which does not entirely and/or necessarily apply to Actos.

9. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer, and is still caused to suffer serious and dangerous side effects of ingesting Actos including, but not limited to, bladder cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences. Plaintiff herein has sustained certain of the above health consequences due to his use of Actos.

10. Defendants concealed their knowledge of the defects in their product from Plaintiff, Plaintiff's physicians, hospitals, pharmacists, the FDA, and the public in general.

11. Consequently, Plaintiff seeks compensatory damages as a result of Plaintiff's use of Actos, which has caused Plaintiff to suffer from bladder cancer, as well as other severe personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

PARTY PLAINTIFF

12. Plaintiff, James Shantz, is a citizen of the United States of America, and is a resident of Butler County, Pennsylvania.

13. Plaintiff was born on July 19, 1939.

14. Plaintiff first began using Actos on or about 2006.

15. As a result of using Defendants' Actos, Plaintiff was caused to develop bladder cancer on or about April 2016, requiring surgery, which caused him to sustain severe and permanent personal injuries, pain, suffering, and emotional distress.

16. The injuries and damages sustained by Plaintiff were caused by Defendants' Actos.

PARTY DEFENDANTS

17. Takeda Pharmaceuticals USA, Inc. f/k/a Takeda Pharmaceuticals North America, Inc. is a Delaware corporation which has its principal place of business at One Takeda Parkway Deerfield, IL 60015.

18. Takeda Pharmaceuticals USA, Inc. f/k/a Takeda Pharmaceuticals North America, Inc. is a wholly owned subsidiary of Takeda Pharmaceutical Company Limited.

19. Takeda Pharmaceuticals USA, Inc. f/k/a Takeda Pharmaceuticals North America, Inc. has transacted and conducted business within the Commonwealth of Pennsylvania.

20. Takeda Pharmaceuticals USA, Inc. f/k/a Takeda Pharmaceuticals North America, Inc. has derived substantial revenue from goods and products used in the Commonwealth of Pennsylvania.

21. Takeda Pharmaceuticals USA, Inc. f/k/a Takeda Pharmaceuticals North America, Inc. expected or should have expected their acts to have consequences within the Commonwealth of Pennsylvania and derived substantial revenue from interstate commerce.

22. Takeda Pharmaceuticals America, Inc. is a Delaware Corporation which has its principal place of business at One Takeda Parkway Deerfield, IL 60015.

23. Takeda Pharmaceuticals America, Inc. is a wholly owned subsidiary of Takeda Pharmaceuticals USA, Inc. f/k/a Takeda Pharmaceuticals North America, Inc.

24. Takeda Pharmaceuticals America, Inc. has derived substantial revenue from goods

and products used in the Commonwealth of Pennsylvania.

25. Takeda Pharmaceuticals America, Inc. expected or should have expected their acts to have consequences within the Commonwealth of Pennsylvania and derived substantial revenue from interstate commerce.

26. Takeda Global Research & Development Center, Inc. is a Delaware corporation which has its principal place of business at One Takeda Parkway, Deerfield, IL 60015.

27. Takeda Global Research & Development Center, Inc. is a wholly-owned subsidiary of Takeda Pharmaceuticals USA, Inc.

28. Takeda Global Research & Development Center, Inc. has transacted and conducted business within the Commonwealth of Pennsylvania.

29. Takeda Global Research & Development Center, Inc. has derived substantial revenue from goods and products used in the Commonwealth of Pennsylvania.

30. Takeda Global Research & Development Center, Inc. expected or should have expected their acts to have consequences within the Commonwealth of Pennsylvania and derived substantial revenue from interstate commerce.

31. Takeda Pharmaceuticals International, Inc. is a Delaware corporation with its principal place of business located at One Takeda Parkway, Deerfield, IL 60015.

32. Takeda Pharmaceuticals International, Inc. is a wholly-owned subsidiary of Takeda Pharmaceuticals USA, Inc.

33. Takeda Pharmaceuticals International, Inc. has transacted and conducted business within the Commonwealth of Pennsylvania.

34. Takeda Pharmaceuticals International, Inc. has derived substantial revenue from goods and products used in the Commonwealth of Pennsylvania.

35. Takeda Pharmaceuticals International, Inc. expected or should have expected their acts to have consequences within the Commonwealth of Pennsylvania and derived substantial revenue from interstate commerce.

36. The above Defendants are collectively referred to herein as “Takeda” or “Defendants”.

37. Defendants, directly or through their agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed, promoted and sold ACTOS for the treatment of Type 2 Diabetes Mellitus.

38. ACTOS was launched by Takeda Pharmaceuticals USA, Inc. f/k/a Takeda Pharmaceuticals North America, Inc. in 1999.

39. According to the American Diabetes Association, Type 2 diabetes is the most common form of diabetes. Type 2 diabetes develops when the body does not produce enough insulin or does not efficiently use the insulin that it does produce. Type 1 diabetes occurs when the body does not produce any insulin at all. Insulin is necessary for the body to be able to use glucose for energy.

40. ACTOS was approved by the Food and Drug Administration (“FDA”) in July of 1999 to treat Type 2 diabetes. ACTOS is in a class of insulin-sensitizing diabetes agents known as thiazolidinediones (“TZDs”).

41. ACTOS exerts its antihyperglycemic effect only in the presence of endogenous insulin. Therefore, ACTOS is only used to treat Type 2 diabetes and should not be used to treat Type 1 diabetes.

42. ACTOS is sold as a single ingredient product under the brand name ACTOS, and it is also sold in combination with metformin (Actoplus Met, Actoplus Met XR) and in combination with glimepiride (Duetact).

43. As a result of the defective nature of ACTOS, persons who were prescribed and ingested ACTOS for more than twelve (12) months, including Plaintiff, have suffered and may continue to suffer from bladder cancer.

44. Defendants concealed and continue to conceal their knowledge that ACTOS can cause bladder cancer from Plaintiff, other consumers, and the medical community. Specifically, Defendants have yet to adequately inform consumers and the prescribing medical community about the risks of bladder cancer with use of ACTOS for more than twelve (12) months.

45. As a result of Defendants' actions and inactions, Plaintiff was injured due to his ingestion of ACTOS, which caused and will continue to cause Plaintiff various injuries and damages.

46. Prior to ACTOS being approved by the FDA, a two-year carcinogenicity study was conducted on male and female rats. Drug-induced tumors were observed in male rats receiving doses of ACTOS that produced blood drug levels equivalent to those resulting from a clinical dose.

47. In 2005, the results of a three-year study were published that prospectively looked at the impact in total mortality and macrovascular morbidity using ACTOS. Dormandy J.A., et al. *Secondary Prevention of Macrovascular Events in Patients with Type 2 Diabetes in the PROactive Study (PROspective PioglitAzone Clinical Trial In MacroVascular Events): a Randomized Controlled Trial*, Lancet, 266:1279-1289 (2005).

48. The PROactive study was looking at cardiovascular events and outcomes. However, the study demonstrated a higher percentage of bladder cancer cases in patients receiving ACTOS versus comparators. This information was not included in the published Dormandy paper.

49. A three-year liver safety study was also performed, and according to the FDA, that study also demonstrated a higher percentage of bladder cancer cases in patients receiving ACTOS versus comparators.

50. On September 17, 2010, the FDA issued a Safety Announcement stating it was undertaking a review of the data from an ongoing, ten-year epidemiological study being conducted by Kaiser Permanente to evaluate the association between ACTOS and bladder cancer. The planned five-year interim analysis demonstrated that the risk of bladder cancer increases with increasing dose and duration of ACTOS use, reaching statistical significance after 24 months.

51. Despite this finding by the FDA, Robert Spanheimer, Vice President of Medical and Scientific Affairs for Takeda, claimed to Reuters that the Kaiser Permanente study has not shown a risk to patients of bladder cancer or other cancers from ACTOS.

52. In early 2011, the American Diabetes Association published *Assessing the Association of Pioglitazone Use and Bladder Cancer Through Drug Adverse Event Reporting*, Piccinni, et al. *Diabetes Care*, 34:1369-1371 (June 2011), published ahead of print April 22, 2011. This study looked at adverse events reports made to the FDA between 2004 and 2009. The conclusion of that study was that “[i]n agreement with preclinical and clinical studies, AERS analysis is consistent with an association between pioglitazone and bladder cancer. This issue needs constant epidemiologic surveillance and urgent definition by more specific studies.”

53. On June 9, 2011, the European Medicines Agency announced that it had been informed by the French Medicines Agency of its decision to suspend the use of pioglitazone-containing medicines in France while awaiting the outcome of the ongoing European review.

54. France's decision was based upon a retrospective cohort study in France using the French National Health Insurance Plan which demonstrated a statistically significant increase in the risk for bladder cancer in males exposed to ACTOS for more than a year. The French cohort included 1.5 million patients with diabetes that were followed for 4 years (2006-2009).

55. On June 10, 2011, Reuters published that Germany had joined France in suspending the use of ACTOS after Germany's Federal Institute for Drugs and Medical Devices ("BfArM") reviewed the results of the French study. BfArM recommended that doctors should not put new patients on pioglitazone.

56. On June 15, 2011, the FDA issued another Safety Announcement stating that "use of the diabetes medication ACTOS (pioglitazone) for more than one year may be associated with an increased risk of bladder cancer." The FDA ordered information about this risk to be added to the *Warnings and Precautions* section of the label for pioglitazone-containing medicines.

57. The FDA reported that the risk of bladder cancer increased with increasing dose and duration of pioglitazone use. When compared to persons never exposed to pioglitazone, persons exposed to pioglitazone therapy for longer than 12 months was associated with a 40% increase in risk. Based on this data, the FDA calculated that therapy with ACTOS for longer than 12 months was associated with 27.5 excess cases of bladder cancer per 100,000 person-years follow-up, compared to those who never used pioglitazone.

58. On July 12, 2011, Takeda Pharmaceutical Company Limited issued a recall on ACTOS in France.

59. As the manufacturers and/or distributors of ACTOS, Defendants knew or should have known that ACTOS use for longer than 12 months was associated with bladder cancer. Instead, Defendants promoted ACTOS as a safe and effective treatment for Type 2 diabetes.

60. Piccinni, et al. analyzed the association between antidiabetic drugs and bladder cancer by reviewing reports from the FDA Adverse Event Reporting System (“AERS”) between 2004 and 2009. The association was analyzed by the case/non-case methodology. There were 31 recorded reports of bladder cancer in patients using pioglitazone. Piccinni’s results indicated that the reporting odds ratio for pioglitazone was indicative of a “definite risk.” *Assessing the Association of Pioglitazone Use and Bladder Cancer Through Drug Adverse Event Reporting*, Piccinni, et al. *Diabetes Care*, 34:1369-1371 (June 2011), published ahead of print April 22, 2011.

61. Despite its knowledge of this dangerous side effect that can result from ACTOS use, Defendants refused to warn patients, physicians and the medical community about the risk of bladder cancer.

62. ACTOS is one of Defendants’ top selling drugs. Upon information and belief, in the last year, the medication had global sales of \$4.8 billion and accounted for approximately 27% of Takeda’s revenue. In 2008, ACTOS was the tenth best-selling medication in the United States.

63. Consumers, including Plaintiff, who have used ACTOS for treatment of Type 2 diabetes, have several alternative safer products available to treat the conditions and have not been adequately warned about the significant risks and lack of benefits associated with long-term ACTOS therapy.

64. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and his physicians the true and significant risks associated with long-term ACTOS use.

65. As a result of Defendants' actions, Plaintiff and his prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this Complaint and that those risks were the direct and proximate result of Defendants' acts, omissions, and misrepresentations.

66. Plaintiff was prescribed and began taking ACTOS upon direction of his physicians.

67. Plaintiff subsequently developed bladder cancer.

68. As a direct result of being prescribed ACTOS for many years, Plaintiff has been permanently and severely injured, having suffered serious consequences from long-term ACTOS use.

69. Plaintiff requires, and will in the future require, ongoing medical care and treatment.

70. Plaintiff has endured and continues to suffer mental anguish and the psychological trauma of living with the knowledge that he has suffered serious and dangerous side effects including, bladder cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of redeveloping cancer.

71. Plaintiff would not have used ACTOS had Defendants properly disclosed the risks associated with its long-term use.

FEDERAL REQUIREMENTS

72. Plaintiff incorporates all of the previous paragraphs of this Complaint as if fully stated herein.

73. Defendants had an obligation to comply with the law in the manufacture, design and sale of Actos.

74. The Defendants violated the Federal Food, Drug and Cosmetic Act, found at 21 U.S.C. § 301, *et seq.*

75. With respect to the prescription drug Actos, the Defendants failed or may have failed to comply with all federal standards applicable to the sale of the prescription drugs including, but not limited to, one or more of the following violations:

- a) The prescription drug Actos is adulterated pursuant to 21 U.S.C. § 351 because, among other things, it fails to meet established performance standards, and/or the methods, facilities, or controls used for its manufacture, packing, storage or installation is not in conformity with federal requirements, as required by 21 U.S.C. § 351;
- b) The prescription drug Actos is adulterated pursuant to 21 U.S.C. § 351 because, among other things, its strength differs from or its quality or purity falls below the standard set forth in the official compendium for Actos and such deviations are not plainly stated on their labels, as required by 21 U.S.C. § 351;
- c) The prescription drug Actos is misbranded pursuant to 21 U.S.C. § 352 because, among other things, its labeling is false or misleading;
- d) The prescription drug Actos is misbranded pursuant to 21 U.S.C. § 352 because words, statements, or other information are not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use, as required by 21 U.S.C. § 352;
- e) The prescription drug Actos is misbranded pursuant to 21 U.S.C. § 352 because the labeling does not bear adequate directions for use, and/or the labeling does not bear adequate warnings against use where its use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such a manner and form as are necessary for the protection of users, as required by 21 U.S.C. § 352;

- f) The prescription drug Actos is misbranded pursuant to 21 U.S.C. § 352 because it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof, as prohibited by 21 U.S.C. § 352;
- g) The prescription drug Actos does not contain adequate directions for use pursuant to 21 C.F.R. § 201.5, because, among other reasons, of omission, in whole or in part, or incorrect specification of (a) statements of all conditions, purposes, or uses for which it is prescribed, recommended or suggested in their oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drugs are commonly used, (b) quantity of uses, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions, (c) frequency of administration or application, (d) duration or administration or application, and/or (e) route or method of administration or application, as required by 21 C.F.R. § 201.5;
- h) The Defendants violated 21 C.F.R. § 201.56 because the labeling of Actos was not informative and accurate;
- i) The prescription drug Actos is misbranded pursuant to 21 C.F.R. § 201.56 because the labeling was not updated as new information became available that caused the labeling to become inaccurate, false, or misleading, as required by 21 C.F.R. § 201.56;
- j) The Defendants violated 21 C.F.R. § 201.57 because they failed to identify specific tests needed for selection or monitoring of patients who took the prescription drug Actos, as required by 21 C.F.R. § 201.57;
- k) The Defendants violated 21 C.F.R. § 201.57 because the safety considerations regarding the prescription drug Actos are such that the drug should be reserved for certain situations, and the Defendants failed to state such information, as required by 21 C.F.R. § 201.57;
- l) The prescription drug Actos is mislabeled pursuant to 21 C.F.R. § 201.57 because the labeling fails to describe serious adverse reactions and potential safety hazards, limitations in use imposed by it, and steps that should be taken if they occur, as required by 21 C.F.R. § 201.57;

- m) The prescription drug Actos is mislabeled pursuant to 21 C.F.R. § 201.57 because the labeling was not revised to include a warning as soon as there was reasonable evidence of an association of a serious hazard with the drug, as required by 21 C.F.R. § 201.57;
- n) The Defendants violated 21 C.F.R. § 201.57 because the labeling failed to list the adverse reactions that occur with the prescription drug Actos and other drugs in the same pharmacologically active and chemically related class, as required by 21 C.F.R. § 201.57;
- o) The prescription drug Actos is mislabeled pursuant to 21 C.F.R. § 201.57 because the labeling does not state the recommended usual dose, the usual dose ranger, and, is appropriate, an upper limit beyond which safety and effectiveness have not been established, as required by 21 C.F.R. § 201.57;
- p) The prescription drug Actos violates 21 C.F.R. § 210.1 because the process by which it was manufactured, processed, and/or held fails to meet the minimum current good manufacturing practice of methods to be used in, and the facilities and controls to be used for, the manufacture, packing, or holding of a drug to assure that it meets the requirements as to safety and meets the quality and purity characteristic that they purport or are represented to possess, as required by 21 C.F.R. § 210.1;
- q) The prescription drug Actos violates 21 C.F.R. § 210.122 because the labeling and packaging materials do not meet the appropriate specifications, as required by 21 C.F.R. § 210.122;
- r) The prescription drug Actos violates 21 C.F.R. § 211.165 because the test methods employed by the Defendants are not accurate, sensitive, specific, and/or reproducible and/or such accuracy, sensitivity, specificity, and/or reproducibility of test methods have not been properly established and documented, as required by 21 C.F.R. § 211.165;
- s) The prescription drug Actos violates 21 C.F.R. § 211.165 in that the prescription drug Actos fails to meet established standards or specifications and any other relevant quality control criteria, as required by 21 C.F.R. § 211.165;

- t) The prescription drug Actos violates 21 C.F.R. § 211.198 because the written procedures describing the handling of all written and oral complaints regarding the prescription drug Actos were not followed, as required by 21 C.F.R. § 211.198;
- u) The prescription drug Actos violates 21 C.F.R. § 310.303 in that the prescription drug Actos is not safe and effective for its intended use, as required by 21 C.F.R. § 310.303;
- v) The Defendants violated 21 C.F.R. § 310.303 because the Defendants failed to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are or may be grounds for suspending or withdrawing approval of the application to the FDA, as required by 21 C.F.R. § 310.303;
- w) The Defendants violated 21 C.F.R. §§ 310.305 and 314.80 by failing to report adverse events associated with the prescription drug Actos as soon as possible, or at least within 15 days of the initial receipt by the Defendants of the adverse drug experience, as required by 21 C.F.R. § 310.305 and 314.80;
- x) The Defendants violated 21 C.F.R. §§ 310.305 and 314.80 by failing to conduct an investigation of each adverse event associated with the prescription drug Actos, and evaluating the cause of the adverse event, as required by 21 C.F.R. §§ 310.305 and 314.80;
- y) The Defendants violated 21 C.F.R. §§ 310.305 and 314.80 by failing to promptly investigate all serious, unexpected adverse drug experiences and submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA, as required by 21 C.F.R. §§ 310.305 and 314.80;
- z) The Defendants violated 21 C.F.R. §§ 310.305 and 314.80 by failing to keep records of the unsuccessful steps taken to seek additional information regarding serious, unexpected adverse drug experiences, as required by 21 C.F.R. §§ 310.305 and 314.80;

- aa) The Defendants violated 21 C.F.R. §§ 310.305 and 314.80 by failing to identify the reports they submitted properly, such as by labeling them as “15-day Alert report,” or “15-day Alert follow up”, as required by 21 C.F.R. §§ 310.305 and 314.80;
- bb) The Defendants violated 21 C.F.R. § 312.32 because they failed to review all information relevant to the safety of the prescription drug Actos including information received by the Defendants from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers, as well as reports from foreign regulatory authorities that have not already been previously reported to the agency by the sponsor, as required by 21 C.F.R. § 312.32;
- cc) The Defendants violated 21 C.F.R. § 314.80 by failing to provide periodic reports to the FDA containing (a) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval, (b) an Adverse Reaction Report for each adverse drug experience not already reported under the Post marketing 15-day Alert report, and/or (c) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated), as required by 21 C.F.R. § 314.80; and,
- dd) The Defendants violated 21 C.F.R. § 314.80 by failing to submit a copy of the published article from scientific or medical journals along with one or more 15-day Alert reports based on information from the scientific literature, as required by 21 C.F.R. § 314.80.

76. The above-referenced statutes and regulations comprise the standard of care for the Defendants, which were intended for the benefit of individual consumers such as the Plaintiff, which the Defendants failed to meet, making the Defendants liable under Pennsylvania law.

COUNT I – STRICT LIABILITY

77. Plaintiff incorporates by reference each preceding paragraph, as if they were set forth herein more fully at length.

78. The dangerous propensities of Actos were known to Defendants, or reasonably and scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold their respective products, and not known to ordinary physicians who would be expected to prescribe the drug for their patients.

79. The Actos products as distributed by Defendants were defective and unreasonably dangerous prescription drug products, as Defendants failed to provide appropriate and adequate warnings and instructions to render the products reasonably safe for their ordinary, intended, and reasonably foreseeable uses; in particular – the common, foreseeable, and intended use of Actos therapy, as long-term maintenance for Type 2 Diabetes Mellitus.

80. At all times relevant to this action, Defendants manufactured, supplied, and/or sold Actos in a defective and dangerous condition, as described above, to physicians, including Plaintiff's physician.

81. As a direct, foreseeable, and proximate result of Defendants' defective Actos product, Plaintiff suffered grievous bodily injuries and consequent economic and other losses, as referenced above, when his physicians, lacking adequate warnings and other appropriate facts that were misrepresented or omitted from the information (if any) Defendants provided to physicians for their respective products, prescribed for Plaintiff the use of Actos for a prolonged and unwarranted period of time exceeding twelve (12) months.

82. By reason of the foregoing acts and omissions, Plaintiff demands judgment against the Defendants, individually, jointly and severally for compensatory damages in a sum in excess of \$75,000.00 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as this Honorable Court deems necessary.

COUNT II - NEGLIGENCE

83. Plaintiff incorporates all of the previous paragraphs of this Complaint, as if fully stated herein.

84. Defendants had a duty to exercise reasonable care in the design, research, manufacture, marketing, supply, promotion, packaging, sale and/or distribution of Actos into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous side effects.

85. Defendants failed to exercise ordinary care in the design, research, manufacture, marketing, supply, promotion, packaging, sale, testing, quality assurance, quality control, and/or distribution of Actos into interstate commerce in that the Defendants knew, or should have known, that using Actos created a high risk of unreasonable, dangerous side effects, including bladder cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and the fear of redeveloping cancer.

86. The negligence of the Defendants, their agents, servants, and/or employees, included, but was not limited to, the following acts and/or omissions:

- a) Manufacturing, producing, promoting, formulating, creating, and/or designing Actos without thoroughly testing it;
- b) Manufacturing, producing, promoting, formulating, creating, and/or designing Actos without adequately testing it;
- c) Not conducting sufficient testing programs to determine whether or not Actos was safe for use in that the Defendants herein knew, or should have known, that Actos was unsafe and unfit for use by reason of the dangers it posed to its users;

- d) Selling Actos without making proper and sufficient tests to determine the dangers it posed to its users;
- e) Negligently failing to adequately and correctly warn the Plaintiff, the public, the medical and healthcare profession, and the FDA of the dangers of Actos;
- f) Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, Actos;
- g) Failing to test Actos and/or failing to adequately, sufficiently and properly test Actos;
- h) Negligently advertising and recommending the use of Actos without sufficient knowledge as to its dangerous propensities;
- i) Negligently representing that Actos was safe for use for its intended purpose, when, in fact, it was unsafe;
- j) Negligently representing that Actos had equivalent safety and efficacy as other forms of Type 2 Diabetes Mellitus treatment;
- k) Negligently designing Actos in a manner which was dangerous to its users;
- l) Negligently manufacturing Actos in a manner which was dangerous to its users;
- m) Negligently assembling Actos in a manner which was dangerous to its users;
- n) Concealing information concerning FDA warnings from the Plaintiff in knowing that Actos was unsafe, dangerous, and/or non-conforming with FDA regulations;
- o) Improperly concealing and/or misrepresenting information to the Plaintiff, healthcare professionals, and/or the FDA, concerning the severity of risks and dangers of Actos compared to other forms of Type 2 Diabetes Mellitus treatment.

87. Defendants under-reported, underestimated and downplayed the serious dangers of Actos.

88. Defendants negligently compared the safety risk and/or dangers of Actos with other forms of Type 2 Diabetes Mellitus treatment.

89. Defendants were negligent in the design, research, supply, manufacture, promotion, packaging, distribution, testing, advertising, warning, marketing and sale of Actos in:

- a) Failing to use due care in designing and manufacturing Actos so as to avoid the aforementioned risks to individuals when Actos was used for the treatment of Type 2 Diabetes Mellitus;
- b) Failing to accompany their product with proper and/or accurate warnings regarding all possible adverse side effects associated with the use of Actos;
- c) Failing to accompany their product with proper warnings regarding all possible adverse side effects concerning the failure and/or malfunction of Actos;
- d) Failing to accompany their product with accurate warnings regarding the risks of all possible adverse side effects concerning Actos;
- e) Failing to warn Plaintiff of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;
- f) Failing to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Actos;
- g) Failing to warn Plaintiff, prior to actively encouraging the sale of Actos, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects; and,
- h) Were otherwise careless and/or negligent.

90. Despite the fact that Defendants knew, or should have known, that Actos caused unreasonably dangerous side effects, Defendants continued and continue to market, manufacture, distribute and/or sell Actos to consumers, including the Plaintiff.

91. Defendants knew or should have known that consumers such as the Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

92. Defendants' negligence was the proximate cause of Plaintiff's injuries, harm and economic loss, which Plaintiff suffered and/or will continue to suffer.

93. As a result of Defendants' foregoing acts and omissions, the Plaintiff suffered serious and dangerous side effects including, bladder cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of redeveloping cancer.

94. As a result of Defendants' foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff will in the future be required to obtain further medical and/or hospital care, attention and services.

95. By reason of Defendants' foregoing acts and omissions, Plaintiff demands judgment against the Defendants, individually, jointly and severally for compensatory damages in a sum in excess of \$75,000.00 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as this Honorable Court deems necessary.

COUNT III – BREACH OF THE EXPRESS WARRANTY

96. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully

stated herein.

97. Defendants expressly warranted that Actos was safe and well accepted by all users.

98. Actos does not conform to these express representations because Actos is not safe and has numerous serious side effects, many of which were not accurately warned about by the Defendants. As a direct and proximate result of the breach of said warranties, Plaintiff James Shantz suffered and/or will continue to suffer severe and permanent personal injuries, harm and economic loss.

99. Plaintiff did rely on the express warranties of the Defendants when choosing to use the pharmaceutical drug Actos.

100. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of the Defendants for use of Actos in recommending, prescribing and/or dispensing the pharmaceutical drug Actos.

101. The Defendants herein breached the aforementioned express warranties, as their drug Actos was defective.

102. Defendants expressly represented to Plaintiff, his physicians, healthcare providers and/or the FDA, that Actos was safe and fit for use for its intended purposes, that it was of merchantable quality, that it did not produce any dangerous side effects in excess of those risks associated with other forms of Type 2 Diabetes Mellitus, that the side effects it did produce were accurately reflected in the warnings and that it was adequately tested and fit for its intended use.

103. Defendants knew, or should have known that, in fact, said representations and warranties were false, misleading and untrue, in that Actos was not safe and fit for the use intended, and, in fact, produced serious injuries to its users that were not accurately identified and represented by the Defendants.

104. As a result of Defendants' foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects including, bladder cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of redeveloping cancer.

105. By reason of the foregoing, Plaintiff has been severely and permanently injured, as he will require more constant and continuous medical monitoring and treatment than prior to his use of Defendants' drug Actos.

106. As a result of Defendants' foregoing acts and omissions, Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed, believes and further alleges that he will in the future be required to obtain further medical and/or hospital care, attention and services.

107. By reason of the foregoing acts and omissions, Plaintiff demands judgment against the Defendants, individually, jointly and severally for compensatory damages in a sum in excess of \$75,000.00 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as this Honorable Court deems necessary.

COUNT IV – BREACH OF IMPLIED WARRANTIES

108. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if stated more fully herein.

109. At all relevant times, Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Actos and/or have acquired the Defendants who have manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Actos, as treatment for Type 2

Diabetes Mellitus.

110. At the time Defendants marketed, sold and distributed Actos for use by Plaintiff, Defendants knew of the use for which Actos was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

111. The Defendants impliedly represented and warranted to the users of Actos and their physicians, healthcare providers, and/or the FDA that Actos was safe and of merchantable quality and fit for the ordinary purpose for which said product was to be used.

112. The aforementioned representations and warranties of the Defendants were false, misleading, and inaccurate in that Actos was unsafe, unreasonably dangerous, improper, not of merchantable quality and defective.

113. Plaintiff and/or members of the medical community and/or healthcare professionals relied on the aforementioned implied warranty of merchantability of fitness for a particular use and purpose.

114. Plaintiff and Plaintiff's physicians and healthcare professionals reasonably relied upon the skill and judgment of the Defendants as to whether Actos was of merchantable quality and safe and fit for its intended use.

115. Actos was injected into the stream of commerce by the Defendants in a defective, unsafe, and inherently dangerous condition, and the products and materials were expected to and did reach users, handlers, and persons, including Plaintiff, coming into contact with said products without substantial change in the condition in which it was sold.

116. The Defendants herein breached the aforementioned implied warranties as the pharmaceutical drug Actos was not fit for its intended purposes and uses.

117. As a result of Defendants' foregoing acts and omissions, Plaintiff was caused to

suffer serious and dangerous side effects, including bladder cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of redeveloping cancer.

118. As a result of Defendants' foregoing acts and omissions, Plaintiff requires and/or will require more health care services and did incur medical, health, incidental and related expenses. Plaintiff is informed, believes and further alleges that he will in the future be required to obtain further medical and/or hospital care, attention and services.

119. By reason of the foregoing acts and omissions, Plaintiff demands judgment against the Defendants, individually, jointly and severally for compensatory damages in a sum in excess of \$75,000.00 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as this Honorable Court deems necessary.

COUNT V – NEGLIGENT MISREPRESENTATION

120. Plaintiff incorporates all of the preceding paragraphs of this Complaint, as if stated more fully herein.

121. Defendants had a duty to represent to the medical and healthcare community, and to the Plaintiff, the FDA and the public in general, that the pharmaceutical drug Actos had been tested and found to be safe and effective for the treatment of Type 2 Diabetes Mellitus.

122. The representations made by the Defendants were, in fact, false.

123. Defendants failed to exercise ordinary care in the representation of Actos, while involved in its manufacture, sale, testing, quality assurance, quality control, and/or distribution of said product into interstate commerce in that the Defendants negligently misrepresented Actos' high risk of unreasonable, dangerous side effects.

124. Defendants breached their duty in representing Actos' serious side effects to the medical and healthcare community, to the Plaintiff, the FDA and the public in general.

125. As a result of Defendants' foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including bladder cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of redeveloping cancer.

126. As a result of Defendants' foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed, believes and further alleges that he will in the future be required to obtain further medical and/or hospital care, attention and services.

127. By reason of Defendants' foregoing acts and omissions, Plaintiff demands judgment against the Defendants, individually, jointly and severally for compensatory damages in a sum in excess of \$75,000.00 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as this Honorable Court deems necessary.

PUNITIVE DAMAGES

128. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including the Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public, the health and medical community, Plaintiff, and the FDA. Defendants made conscious decisions not to redesign, re-label, warn, or inform the unsuspecting consuming public of the aforementioned damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against the Defendants on each of the above-referenced claims and Causes of Action and as follows:

A. Awarding compensatory damages to Plaintiff for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by the Plaintiff, healthcare costs and medical monitoring, together with interest and costs, as provided by law;

B. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants, who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;

C. Awarding Plaintiff reasonable attorneys' fees;

D. Awarding Plaintiff the costs of these proceedings; and,

E. Such other and further relief as this Court deems just and proper.

PLAINTIFF DEMANDS A TRIAL BY JURY.

Respectfully submitted,

By: /s/ D. Aaron Rihn

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